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*C. R. Bard, Inc. and*  
13 *Bard Peripheral Vascular, Inc.*

14 **IN THE UNITED STATES DISTRICT COURT**  
15 **FOR THE DISTRICT OF ARIZONA**

16 IN RE: Bard IVC Filters Products Liability  
17 Litigation

No. 2:15-MD-02641-PHX-DGC

**DEFENDANTS' RESPONSE IN  
OPPOSITION TO PLAINTIFF'S  
MOTION *IN LIMINE* NO. 11 TO  
EXCLUDE THE SURGICAL  
CONSENT FORM SIGNED BY MS.  
BOOKER**

(Assigned to the Honorable David G.  
Campbell)

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively “Bard”) submit this response in opposition to Plaintiff’s Motion *in Limine* No. 11 and respectfully show the Court as follows:

### **ARGUMENT AND CITATION OF AUTHORITY**

The Plaintiff seeks to exclude the “Permission for Operation And/Or Procedure” form (the “Consent Form”). (*See* Ex. A to Pl.’s Mot.) According to the Plaintiff, the Consent Form did not disclose or warn her of the long-term risks associated with her G2® Filter and is not specific to IVC filter implantation; therefore, she argues she did not consent to the long-term risks associated with her G2® Filter by executing the Consent Form. (*See* Pl.’s Mot. at 2.)

Bard has no intention of arguing that the Consent Form warned the Plaintiff about the potential risks of the G2® Filter. Nonetheless, the Consent Form is still relevant and material to establish that the Plaintiff and her implanting physician, Marcus D’Ayala, M.D. (“Dr. D’Ayala”), discussed a course of treatment that included implanting a G2® Filter, and that the Plaintiff agreed to this course of treatment.

Moreover, the Consent Form the Plaintiff signed contains language that implicitly acknowledges the consumer expectation that there are no guarantees for medical procedures, and by extension, implantable medical devices like the Plaintiff’s G2® Filter. For the reasons set forth below, the Consent Form is admissible pursuant to Federal Rules of Evidence 401, 402, and 403.

#### **A. The Consent Form Speaks for Itself.**

Bard does not claim that by signing the Consent Form the Plaintiff was warned of or consented to any long-term filter risks. Instead, Bard argues that it is entirely relevant to show that the Plaintiff acknowledged her surgical procedure, like all surgical procedures, presented risks.

The Plaintiff signed the Consent Form recognizing that Dr. D’Ayala “fully explained to me the nature and purpose of the operation/procedure and has also informed me of expected benefits and complications, attendant discomforts and risks that may

1 arise....” (*See* Ex. A to Pl.’s Mot. at ¶ 2.) The executed Consent Form also states  
 2 “unforeseen conditions may arise which necessitate procedures different from those  
 3 contemplated. I therefore consent to the performance of additional operations and  
 4 procedures which the above-named physician...may consider necessary.” (*Id.* at ¶ 3.)  
 5 Bard submits that the Consent Form speaks for itself. It demonstrates that the Plaintiff  
 6 acknowledged “unforeseen conditions,” “complications,” and “risks” that may arise as a  
 7 consequence of undergoing the surgical procedure, and that she discussed with Dr.  
 8 D’Ayala his proposed course of treatment and consented to it.

9 **B. The Consent Form is Relevant and Admissible.**

10 Evidence is relevant if it has any tendency to make the existence of any fact that is  
 11 of consequence to the determination of the action more or less probable than it would be  
 12 without the evidence. *See* Fed. R. Evid. 401. As discussed, the executed Consent Form is  
 13 relevant to show that the Plaintiff was aware the surgical procedure posed risks, and that  
 14 she and Dr. D’Ayala discussed the “expected benefits and complications” of this proposed  
 15 course of medical treatment prior to the surgery.

16 Nonetheless, the Plaintiff argues that the Consent Form signed prior to the  
 17 procedure implanting the very device at issue in this case “has no relevance to the issues”  
 18 since it is “not IVC, much less Bard, specific.” (Pl.’s Mot. at 2.) However, the Plaintiff’s  
 19 executed consent, together with Dr. D’Ayala’s deposition testimony, establish that she and  
 20 Dr. D’Ayala discussed his proposed treatment plan, and that she agreed to it, whether or  
 21 not filter-specific risks were listed on the actual form.

22 Furthermore, Dr. D’Ayala was aware of known complications with all IVC filters,  
 23 including fracture and migration, at the time he implanted the Plaintiff’s filter. Dr.  
 24 D’Ayala testified: (1) that he had conversation with the Plaintiff prior to the implant  
 25 procedure obtaining her informed consent; (2) that all IVC filters carry risks, including  
 26 fracture, perforation, migration, and tilt, and that he was aware of those complications when  
 27 he implanted the Plaintiff’s filter; and (3) that he learned about those complications from  
 28 his training, literature, and experience as a physician. *See* March 21, 2017 Dep. Tr.

1 Marcus D'Ayala, M.D., at 47:4-7; 49:3-14; 83:13-18; 93:10 to 98:1-6, attached hereto as  
2 Exhibit A.

3 Although relevant, evidence may be excluded if its probative value is substantially  
4 outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the  
5 jury. *See* Fed. R. Evid. 403. The Plaintiff argues that even if the consent form were  
6 relevant, which it is, "it has no probative value whatsoever." (Pl.'s Mot. at 2.) According  
7 to the Plaintiff, arguing that she in any way "consented" to long-term filter risks by  
8 signing this form would be false and misleading, and has a substantial chance of  
9 confusing the jury. (*Id.*) This is simply incorrect.

10 On the contrary, the Consent Form demonstrates that Dr. D'Ayala and the Plaintiff  
11 engaged in a discussion about his medical recommendation to place a G2® Filter in her  
12 vena cava. Whether or not the form advised the plaintiff of G2®-specific complications is  
13 immaterial because Bard is entitled to rely on implanting physicians, who understand the  
14 known risks and benefits of IVC filters, to discuss those risks with their patients. *See*  
15 *Williams v. Am. Med. Sys.*, 548 S.E.2d 371, 375 (Ga. Ct. App. 2001) ("[W]hen a device  
16 can be prescribed and inserted only by a physician, that treating physician has sole  
17 responsibility for advising the patient of dangers associated with the use of the device.").

18 The Consent Form demonstrates that the Plaintiff was aware of "risks that may  
19 arise" from undergoing the surgical procedure, and that she acknowledged Dr. D'Ayala  
20 "informed me of expected benefits and complications." Thus, it is material to establish  
21 the Plaintiff and her implanting physician discussed a course of medical treatment that  
22 included implanting a Bard G2® Filter, and that the Plaintiff agreed to this course of  
23 treatment. This probative value outweighs any unsubstantiated claims of prejudice and/or  
24 jury confusion asserted by the Plaintiff. Accordingly, the Consent Form is relevant and  
25 admissible evidence. *See* Fed. R. Evid. 401, 402, 403.

### 26 CONCLUSION

27 For these reasons, Bard respectfully requests that the Court deny Plaintiff's Motion  
28 *in Limine* No. 11.

RESPECTFULLY SUBMITTED this 9th day of February, 2018.

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 9th day of February, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.  
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